

Application no. 10/614,255  
Filed July 3, 2003



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
APPLICATION FOR UNITED STATES PATENT

INVENTOR: MARY W. EUBANKS  
TITLE: METHOD AND MATERIALS FOR INTROGRESSION OF NOVEL GENETIC  
VARIATION IN MAIZE

JFW



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August 12, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: METHOD AND MATERIALS FOR INTROGRESSION OF NOVEL GENETIC  
VARIATION IN MAIZE

Application No. 10/614,255

Inventor: Mary W. Eubanks

Filing Date: 07/03/2003

Group Art Unit: 1638

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**RESPONSE TO INTERVIEW SUMMARY, OFFICE ACTION, AND AMENDMENTS  
TO CLAIMS**

Dear Examiner Robinson:

This document acknowledges receipt of the interview summary dated 6 June, 2006, and responds to the official action dated 16 June, 2006, in which claims were objected to according to: (1) wording informalities in the claims; (2) nonstatutory double patenting; (3) written description (35 USC § 112); (4) enablement (35 USC § 112), (5) claim rejections (35 USC § 102), and (6) new claim rejections (35 USC § 102).

**INTERVIEW SUMMARY**

The applicant acknowledges the Interview Summary of the telephonic interview on 1 June 2006 with Examiners Keith O. Robinson and David H. Kruse, and the Applicant Mary W. Eubanks. The Examiners explained that a terminal disclaimer would obviate the double patenting objection to claims 2-6 and claims 8-12, which are dependent on claim 2. They indicated the Applicant needs to further clarify that one or more markers will be in every plant produced by the process in order to overcome the written description and enablement rejections. They recommended the Applicant submit a copy of the deposit statement for ATCC75297. The Examiners agreed to withdraw finality and send a new non-final rejection to bring U.S. Patent 5,330,547 to record. The Examiners agreed to propose allowable claims in the new office action.

**OFFICE ACTION RESPONSE****(1) Wording informalities in the Claims**

Claims objected to because of informalities have been revised according to the Examiner's instructions from "A plant according..." to "The plant according...".

**(2) Double Patenting**

The Examiner rejected claims 2-6, 8-12, and 14 as obviousness-type double patenting of claims 1-9 and 11 of Eubanks U.S. Patent 5,750,828,1998. The Examiner asserts that the restriction fragments in claim 2 of this application would occur in any form of mitotic or meiotic cell division and replication in the plant cell cycle, and thus, would not make the instant claims of this application non-obvious. The applicant requests cancellation of claims 2-6, 8-12, and 14. The applicant requests cancellation of claims 2-22 and that new claims 24-35 be entered. This omits claims 2-6, 8-14 dependent on claim 2, and claim 14 in order to overcome the double patenting objection. Therefore, a terminal disclaimer is not being filed at this time.

For purposes of distinction and clarification in the following discussion, the applicant points out that the specification of U.S. Patent 5,750,828 is restricted to two specific crosses between *Zea diploperennis* and a tetraploid *Tripsacum dactyloides* ( $2n=72$ ) in which the same *Tripsacum dactyloides* plant from a population in Spencer County, Indiana was one of the parents of both the teosinte-*Tripsacum* recombinant plants 'Sun Dance' and "Tripsacorn", which were described in U.S. Patent 5,750,828. Furthermore, the *Zea diploperennis* parents of these same two cultivars in U.S. Patent 5,750,828 were siblings from the same population in Jalisco, Mexico (Iltis, Guzman & Nee accession number 1250). On pages 22 and 27 of the specification of this application, additional teosinte-*Tripsacum* hybrids of quite different parentage are described. For example, on page 22, the *Zea diploperennis* parent (2-4) of the recombinant 'Sun Star' is from a different population in Jalisco, Mexico (R. Guzman M. accession number 777), and its *Tripsacum dactyloides* parent is a diploid ( $2n=26$ ) from a Manhattan, Kansas population. Another example on page 27 describes a recombinant between *Zea diploperennis* and a different *Tripsacum* species, *Tripsacum laxum* from Veracruz, Mexico. It would have been impossible to predict a large number of the same novel restriction fragment length polymorphisms would be shared among teosinte-*Tripsacum* plants of such widely divergent parentage (see Table 2, pages 35-46 of the specification), and that they would be stably inherited in multiple generations of maize X (teosinte-*Tripsacum*) crosses. We did not know and could not possibly have anticipated this unprecedented phenomenon, which covers a broader range of parental and recombinant materials and was discovered subsequent to U.S. Patent 5,750,828.

### **(3) Written Description – 35 USC 112**

It is respectfully argued that subject matter contained in the claims is described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The applicant set forth the specific novel RFLPs in Table 2, pages 35-46, of the specification. One or more of the precise novel RFLPs, i.e. RFLPs not found in maize or the other *Zeas* as described on page 23 of the specification, are shown to occur in four different teosinte-*Tripsacum* crosses specified as 'Sun Dance', '20A', 'Tripsacorn', and 'Sun Star'. These recombinants had at least one parent from a distinctly different plant population, ploidy level, or species. Yet, they all share many of the same novel RFLPs. The

remaining 14 entries in Table 2 are plants derived from crossing maize with a teosinte-*Tripsacum* recombinant. Examination of Table 2 reveals that any teosinte-*Tripsacum* hybrid, or any maize plant crossed with a teosinte-*Tripsacum* hybrid, will contain one or more of the novel RFLPs. One skilled in the art could easily test any plant to see if it contained one or more of these particular novel RFLPs. As indicated on pages 18-19 and pages 21-23 of the specification, the molecular methods used are commonly employed in genetic analysis. How traits are associated with molecular markers and used in recurrent selection breeding is described on page 24, and detailed description of precise phenotypes associated with certain markers is provided on pages 24-29. The method for making the cross pollinations to obtain plants that contain the novel fragments in the claims is described on pages 30-31. Accordingly, the applicant has fully described the process and materials in the claims in such a way that one skilled in the art could do this.

#### **(4) Enablement – 35 USC 112**

It is respectfully argued that subject matter contained in the claims is described in the specification in such a way as to reasonably convey to one skilled in the art to make and use the claimed invention. The specific novel RFLPs are set forth in Tables 2 and 3, pages 35-46 and pages 47-48, respectively, of the specification. One or more of the precise novel restriction fragments, i.e. ones not found in maize or the other *Zeas*, as described on page 23 of the specification, are shown to occur in four different teosinte-*Tripsacum* crosses designated 'Sun Dance', '20A', 'Tripsacorn', and 'Sun Star'. These teosinte-*Tripsacum* crosses have different parents from distinctly different plant populations, ploidy levels, and species. Yet, they all share many of the same novel RFLPs. The remaining 14 entries in Tables 2 and 3 are different maize plants derived from crossing maize with a teosinte-*Tripsacum* hybrid. Examination of Table 2 reveals that any teosinte-*Tripsacum* recombinant plant, or any maize plant crossed with a teosinte-*Tripsacum* recombinant, will contain one or more of the novel RFLPs. It would not require undue trial and error experimentation to make crosses between *Zea diploerennis* and *Tripsacum* sp. to obtain the novel RFLPs described in the specification because anytime a viable hybrid is recovered it contains precise genomic rearrangements that produce one or more of the novel RFLPs in the claims. It would not be necessary to screen the broad genus to possess the

claimed novel restriction fragments for the specified molecular marker-enzyme combinations. The method for making the cross pollinations to obtain hybrid plants that contain one of more of the said novel RFLPs is described on pages 30-31 of the specification. One skilled in the art could easily test the DNA of any plant using restriction analysis of a plant's DNA with any of the enzymes named to produce standard southern blots for in situ hybridization with any of the probes listed to see if the plant contained one or more of the novel RFLPs claimed. As indicated on pages 18-19 and pages 21-23 of the specification, the molecular methods used are commonly employed in genetic analysis. Therefore, the applicant has fully described the process for making and analyzing the product and has enabled one skilled in the art to use the claimed invention.

Furthermore, pages 24-25 of the specification walk anyone skilled in the art through the steps followed to identify specific novel RFLPs associated with an insect resistance trait. This is facilitated by the fact that the teosinte-*Tripsacum* hybrid 'Sun Dance' does not exhibit this phenotype which is found in 'Tripsacorn', "Sun Star", '20A' '2019', '3024', 3028', '3125', '4126'. And 'TC64'. The only possible candidate restriction fragments that can be associated with this trait are ones that only occur in resistant plants. Since 'Sun Dance' was a subject of Eubanks U.S. Patent 5,750,828 and Eubanks (Theor. Appl. Genet. 94:707-712, 1997), this demonstrates how the prior art products of Eubanks U.S. Patent 5,750,828 and Eubanks (Theor. Appl. Genet. 94:707-712, 1997) do not necessarily possess the characteristics of the claimed invention of this application.

Another detailed description of the method for identifying novel restriction fragments associated with an agronomic trait of interest is provided on pages 26-29 of the specification in regard to the marker for aerenchyma. Accordingly, the specification provides all the necessary description for anyone skilled in the art to produce hybrid plants between *Zea diploperennis* and *Tripsacum* sp., how to examine the roots for the presence of aerenchyma, how to screen those plants for novel restriction fragments uniquely associated with the trait, and then to use the method for transferring a trait of interest into a maize plant wherein the trait is associated with one or more of the novel restriction fragments. Although teosinte-*Tripsacum* crosses had been made prior to this application, no one appreciated any of these novel RFLPs existed, much less that any of them were associated with traits of interest and would provide a method to transfer traits of interest into maize using conventional plant breeding techniques.

The American Type Culture Collection maintains a deposit of 2500 seeds of a teosinte-*Tripsacum* hybrid. A copy of the deposit receipt for ATCC 75297 is enclosed. This verifies possession by the inventor, and confirms seed of a teosinte-*Tripsacum* hybrid is publicly available. As stated on page of 53 of the specification, the present invention is not limited in scope by the seeds deposited, since the deposited embodiments are intended as illustrations of the invention and any seeds, cell lines, plant parts, plants derived from tissue culture or seeds which are functionally equivalent are within the scope of this invention. An adequate supply of seed from other crosses, including crosses between *Tripsacum laxum* and *Zea diploperennis*, are available for deposit with the American Type Culture Patent Depository if necessary. The teosinte-*Tripsacum* hybrids are perennials. Clones of the teosinte-*Tripsacum* hybrids referred to in the specification are maintained in a greenhouse and/or an outdoor nurseries in Durham, NC and Austin, TX. Six crosses between teosinte-*Tripsacum* hybrids and maize that are introgressed with novel RFLPs in the claims are also perennials and maintained in the greenhouse and outdoor nurseries. These include 'TC64', '7022', (7022 X Devil Corn), 'B016', and '6021'. While the invention has been described in detail and with reference to specific embodiments thereof, it will be apparent to one skilled in the art that changes and modifications can be made without departing from the spirit and scope of the invention in addition to those shown and described herein. Such modifications are intended to fall within the scope of the claims.

#### **(5) Prior Art – 35 USC § 102**

The applicant respectfully argues that subject matter contained in the claims and described in the specification could not have been anticipated by Eubanks (Theor. Appl. Genet. 94:707-712, 1997). As indicated under "Materials and methods" on page 708, the plants described therein had the same *Tripsacum dactyloides* (2n=72) parent in both crosses and the *Zea diploperennis* parent plants were siblings from the same family (i.e. 'Sun Dance' and 'Tripsacorn'). Page 22 of the specification describes crosses between other *Tripsacum dactyloides* populations, some of which have a different ploidy level (2n = 36). It also describes crosses between other *Tripsacum* species. Some *Zea diploperennis* plants in various crosses also come from a different population from a different geographical region of Jalisco, Mexico. The

same novel RFLPs shared among hybrids with parents of such different backgrounds could never have been predicted based on the prior art cited above. Furthermore, there are no references to crosses between maize and teosinte-*Tripsacum* hybrids. The fact the novel RFLPs would be replicated in very different crosses and stably inherited in maize crosses over multiple generations is completely unexpected. For example, in Table 2, page 44, under probe-enzyme combination BNL5.10-H, "Sun Dance, '20A' and 'Tripsacorn' share a 6.1 kb fragment that is not present in 'Sun Star'. On the other hand, in Table 2, page 39, under probe-enzyme combination CSU585-H, 'Tripsacorn' has an 8.3 kb fragment that is not present in 'Sun Dance', but is present in 'Sun Star'. Therefore, the prior art Eubanks (Theor. Appl. Genet. 94:707-712, 1997) and the products claimed are not necessarily one and the same and are inherently distinct.

#### **(6) New Claims Rejections – 35 USC § 102**

The applicant respectfully points out that subject matter contained in the claims and described in the specification could not possibly have been anticipated by Eubanks (U.S. Patent No. 5,330,547, July 19, 1994). Both recombinant plants described therein ('Sun Dance' and 'Tripsacorn') had the same *Tripsacum dactyloides* ( $2n=72$ ) parent from Spencer County, Indiana, and the *Zea diploperennis* parent plants were siblings from the same family from Jalisco, Mexico (Iltis, Guzman & Nee accession number 1250). Page 22 of the specification describes crosses with other *Tripsacum dactyloides* populations, some of which have a different ploidy level ( $2n = 36$ ) and different provenances. It also describes crosses between other *Tripsacum* species. Some *Zea diploperennis* plants in the different crosses presented in the specification also come from a different population from a different geographical region of Jalisco, Mexico (R. Guzman M. accession number 777). The shared novel RFLPs among recombinants of such different genetic backgrounds could never have been predicted based on the prior art cited above. The fact that the same novel RFLPs would be replicated in progeny of such distinctly different parentage, that the novel fragments would be stably inherited over multiple generations, and they would be associated with different traits was totally unexpected and could not have been anticipated by Eubanks (U.S. Patent No. 5,330,547, July 19, 1994). For example, in Table 2, page 42, under probe-enzyme combination BNL14.07-RI, '20A' has a 6.4 kb fragment that is not present in



'Sun Dance' or 'Tripsacorn', but is present in 'Sun Star'. This evidence shows that the prior art products do not necessarily possess the same characteristics of the claimed product.

## CLAIMS

Please cancel claims 1-22 and enter new claims 23-43. In the office action dated 16 June 2006, the Examiner did not propose allowable claims even though it was indicated he would do so in the summary of the telephonic interview that took place on June 1, 2006. Therefore, based on the telephonic interview summary dated 6 June 2006, the interview discussion, and the applicant's notes from the interview, the applicant offers new claims 23-43. Since the Examiner concluded in the office action that "Claims 13, 16, 17, 18, 19, 20, and 22 are deemed free of prior art given the failure of the prior art to teach or suggest a maize plant that contains one or more restriction fragments, produced by crossing a *Tripsacum*/teosinte hybrid with a maize plant, and wherein the hybrid from said cross is distinguished by the presence of" traits designated in those claims, the new claims incorporate that guidance. The new claims, along with the above detailed responses to the Examiner's objections in regard to wording informalities, double patenting, the written description, enablement, and prior art, are intended to clarify content, obviate the Examiner's objections, and bring the application into proper order for allowance of the claims.

Respectfully submitted,



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